

**PIL Title** : GENOTROPIN  
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**Reason** : To align with current effective LPD

# GENOTROPIN<sup>®</sup> POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Somatropin (5.3 mg, 12 mg)

## What is in this leaflet

1. What GENOTROPIN is used for
2. How GENOTROPIN works
3. Before you use GENOTROPIN
4. How to use GENOTROPIN
5. While you are using it
6. Side Effects
7. Storage and Disposal of GENOTROPIN
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What GENOTROPIN is used for

In children, GENOTROPIN is used to treat growth disturbances:

- If you do not have enough of your own growth hormone.
- If you have Turner syndrome (chromosomal error in girls that can affect growth).
- If you have chronic renal (kidney) insufficiency. As kidneys lose their ability to function normally, this can affect growth.
- If you have Prader-Willi syndrome (a chromosomal disorder). Growth hormone will help you grow taller if you are still growing, and will also improve your body composition.
- If you were small or too light at birth or if you have not been able to catch up or maintain normal growth by four years of age or later.

In adults, GENOTROPIN is used to treat persons with pronounced growth hormone deficiency. This can start during adult life, or it can continue from childhood. If you have been treated with GENOTROPIN for growth hormone deficiency during childhood, your growth hormone status will be retested after completion of growth.

## How GENOTROPIN works

GENOTROPIN is a recombinant human growth hormone (also called somatropin). It has the same structure as natural human

growth hormone, which is needed for bones and muscles to grow. It also helps your fat and muscle tissues to develop in the right amounts. It is a recombinant DNA-derived protein, meaning it is not made from human or animal tissue.

## Before you use GENOTROPIN

### - When you must not use it

Do not take GENOTROPIN if

- You are allergic (hypersensitive) to somatropin or any of the other ingredients of GENOTROPIN.
- You have an active tumour (cancer). Tumours must be inactive and you must have finished your anti-tumour treatment before you start your treatment with GENOTROPIN.
- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, accidental injury or similar conditions).
- You are about to have, or have had, a major operation, or get admitted to hospital for any reason, tell your doctor and remind the other doctors you are using growth hormone.
- GENOTROPIN has been prescribed to stimulate growth but you have already stopped growing (closed epiphyses).

### *Pregnancy and lactation*

You should not use GENOTROPIN if you are pregnant, think you may be pregnant or are trying to become pregnant. Ask your doctor for advice before using this medicine while breast-feeding.

### - Before you start to use it

Talk to your doctor before taking GENOTROPIN:

- If you are receiving GENOTROPIN and thyroid hormone replacement therapy concurrently, your doctor will need to monitor your thyroid function closely.
- If you are diabetic and are receiving insulin therapy, GENOTROPIN may

reduce your insulin sensitivity, tell your doctor. Your dose of insulin may need to be adjusted after GENOTROPIN is initiated.

- If you have severe or reoccurring headache, eye problems, vomiting and nausea, your doctor may examine your eyes to assess if you have increased pressure around your skull. Based on this examination, your doctor will determine whether or not to continue treatment with GENOTROPIN.
- Experience in people above 80 years of age is limited. Elderly persons may be more sensitive to the action of GENOTROPIN and therefore may be more prone to develop side effects.
- If you are suffering from any other critical illness, your doctor will decide on whether this medicine is suitable for you or not by weighing the possible benefit against the potential risk involved.

Children with Prader-Willi syndrome:

- Your doctor will give you diet restrictions to follow to ensure effective weight control before and during treatment with GENOTROPIN.
- Your doctor will assess you for signs of upper airway obstruction, sleep apnoea (where your breathing is interrupted during sleep), or respiratory infection before you start treatment with GENOTROPIN.
- During treatment, if you show signs of upper airway obstruction (including starting to snore or worsening of snoring), your doctor will refer you to an Ear, Nose & Throat (ENT) specialist for an assessment and your treatment with GENOTROPIN may be interrupted. During treatment, your doctor will check you for signs of scoliosis, a type of spinal deformity that might happen during rapid growth.
- During treatment, if you develop a lung infection, tell your doctor so that he can treat the infection.

Children with chronic renal (kidney) insufficiency:

- your doctor should examine your kidney function and verify your growth disturbance by following your growth for a year before starting GENOTROPIN. Medical treatment for your kidney condition should be maintained throughout. GENOTROPIN treatment should be stopped at kidney transplantation.

Children born small or too light at birth:

- Your doctor will check your blood sugar and insulin levels before the start of treatment and every year during treatment.

#### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines when taken with GENOTROPIN may cause GENOTROPIN to be less effective and *vice versa*.

You should inform your doctor if you are taking

- medicines to treat diabetes,
- thyroid hormones,
- steroids to reduce inflammation (corticosteroids),
- sex hormones (for example, oestrogens),
- ciclosporin (a medicine that weakens the immune system after transplantation),
- medicines to control epilepsy (anticonvulsants).

### **How to use GENOTROPIN**

#### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### **Recommended dosage**

The dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Your doctor

will advise you about your individualized dose of GENOTROPIN in milligrams (mg) from either your body weight in kilograms (kg) or your body surface area calculated from your height and weight in square metres (m<sup>2</sup>), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Children with growth hormone deficiency:

0.025-0.035 mg/kg body weight per day or 0.7-1.0 mg/m<sup>2</sup> body surface area per day. Higher doses can be used. When growth hormone deficiency continues into adolescence, GENOTROPIN should be continued until completion of physical development.

Children with Turner syndrome:

0.045-0.050 mg/kg body weight per day or 1.4 mg/m<sup>2</sup> body surface area per day.

Children with chronic renal (kidney) insufficiency:

0.045-0.050 mg/kg body weight per day or 1.4 mg/m<sup>2</sup> body surface area per day). Higher doses may be necessary if the rate of growth is too low. Dosage adjustment may be necessary after 6 months of treatment.

Children with Prader-Willi syndrome:

0.035 mg/kg body weight per day or 1.0 mg/m<sup>2</sup> body surface area per day. The daily dosage should not exceed 2.7 mg. Treatment should not be used in children who have almost stopped growing after puberty.

Children born smaller or lighter than expected and with growth disturbance:

0.035 mg/kg body weight per day or 1.0 mg/m<sup>2</sup> body surface area per day). It is important to continue treatment until final height is reached. Treatment should be discontinued after the first year if you are not responding or if you have reached your final height and stopped growing.

Adults with growth hormone deficiency:

- If you continue GENOTROPIN after treatment during childhood you should start with 0.2-0.5 mg per day.

- If your growth hormone deficiency starts during adult life you should start with 0.15-0.3 mg per day.
- This dosage should be gradually increased according to blood test results as well as clinical response and side effects.

The daily maintenance dose seldom exceeds 1.0 mg per day. Women may require higher doses than men. Dosage should be monitored every 6 months.

Persons above 60 years should start with a dose of 0.1–0.2 mg per day which should be slowly increased according to individual requirements. The minimum effective dose should be used.

The maintenance dose seldom exceeds 0.5 mg per day. Follow the instructions given to you by your doctor.

#### - When to use it

Use as directed by your doctor or pharmacist.

#### - How long to use it

Continue taking GENOTROPIN for as long as your doctor recommends.

#### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Inject the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not inject a double dose to make up for the missed dose.

#### - If you use too much (overdose)

If you inject much more than you should, contact your doctor or pharmacist as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or “not yourself”, and you might faint.

### **While you are using it**

#### - Things you must do

- Take your medicine exactly as your doctor has told you.

- Tell all the doctors, dentists and pharmacists treating you that you are taking GENOTROPIN.
- Tell your doctor immediately if you become pregnant while taking this medication.
- If you are receiving GENOTROPIN for growth hormone deficiency following a previous tumour (cancer), you should be examined regularly for recurrence of the tumour.
- If you have diabetes, you should closely monitor your blood sugar level during treatment with GENOTROPIN and discuss the results with your doctor to determine whether you need to change the dose of your medicines to treat diabetes.
- Tell your doctor if you are taking growth hormone to stimulate growth and walk with a limp, or if you start to limp during your growth hormone treatment due to pain in your hip.
- If your doctor confirms that you have developed muscle pain or disproportionate pain near the injection site because of the preservative metacresol, you should use a GENOTROPIN product without metacresol.

#### Injecting GENOTROPIN:

- GENOTROPIN is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Always inject GENOTROPIN exactly as your doctor has told you. Most people do their injections into their thigh or their bottom. Do your injection in the place you have been shown by your doctor. Fatty tissue of the skin can shrink at the site of injection. To avoid it, use a slightly different place for your injection each time. This gives your skin and the area under your skin time to recover from one injection before it gets another one in the same place. You should check with your doctor or pharmacist if you are not sure. Refer to the instructions for use before using your medicine.
- When using the pre-filled pen GoQuick, a pen injection device or reconstitution

device, the needle must be screwed on before mixing. A new needle must be used for each injection. Needles must not be re-used.

- Preparing the injection: The GoQuick pre-filled pen contains the two-chamber cartridge that has both the growth hormone and the dissolving liquid in it. The growth hormone and the dissolving liquid are mixed together by twisting the cartridge holder (see the detailed steps in the Instructions for Use). A separate device is not needed. The reconstituted solution is almost colourless or slightly opalescent. The reconstituted solution for injection is to be inspected prior to use and only clear solutions without particles should be used.

#### - Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not inject GENOTROPIN to anyone else, even if they have the same symptoms or condition as you.

#### - Things to be careful of

When you are mixing GENOTROPIN, do not shake the solution. Mix it gently. Shaking the solution could make the growth hormone foam and damage the active substance.

#### Driving and using machines

No effects on the ability to drive and use machines have been observed.

#### **Side Effects**

Like all medicines, GENOTROPIN can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Frequent side effects:

Formation of antibodies to the injected growth hormone but these do not seem to stop the growth hormone from working.

In children:

- temporary reactions at the injection site.

In adults:

- numbness/tingling,
- muscle stiffness, joint pain, muscle pain,
- water retention (which shows as puffiness) at the legs.

These symptoms may be seen for the first months of treatment, but they disappear spontaneously or when the dosage is lowered.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

#### **Storage and Disposal of GENOTROPIN**

##### - Storage

Before reconstitution:

Store in a refrigerator (2°C – 8°C), or for a maximum of 1 month at or below 25°C. Keep the two-chamber cartridge/pre-filled pen in the outer carton in order to protect from light.

After reconstitution:

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the two-chamber cartridge/pre-filled pen in the outer carton in order to protect from light.

From a microbiological point of view, once reconstituted, the product may be stored for 4 weeks at 2°C - 8°C. Other in-use storage times and conditions are the responsibility of the user.

##### - Disposal

Any unused product or waste material should be disposed of in accordance with local requirements. Empty GoQuick pre-filled pens should never be refilled and must be properly discarded.

#### **Product Description**

##### - What it looks like

Two-chamber cartridge: Powder and solvent for solution for injection. In the two-chamber cartridge there is a white powder in the front compartment and a clear solution in the rear compartment.

The two-chamber cartridge is supplied for use in a re-usable injection device GENOTROPIN Pen or sealed in a disposable multidose pre-filled pen (GoQuick).

Powder and 1.15 ml solvent in a two-chamber glass cartridge (type I glass) separated by a rubber plunger (bromobutyl). The cartridge is sealed at one end with a rubber disc (bromobutyl) and an aluminium cap and at the other end by a rubber stopper (bromobutyl).

The GENOTROPIN Pens are colour coded, and must be used with the matching colour coded GENOTROPIN two-chamber cartridge to give the correct dose. The GENOTROPIN Pen 5.3 (blue) must be used with GENOTROPIN 5.3 mg cartridge (blue). The GENOTROPIN Pen 12 (purple) must be used with GENOTROPIN 12 mg cartridge (purple).

The 5.3 mg pre-filled pen GoQuick is colour coded blue. The 12 mg pre-filled pen GoQuick is colour coded purple.

- Ingredients

- Active ingredient:  
Somatropin

- Inactive ingredients:

Front compartment (powder):

Glycine  
Mannitol  
Sodium dihydrogen phosphate,  
monohydrate  
Disodium phosphate, dodecahydrate

Rear compartment (solvent):

Water for injections  
Metacresol  
Mannitol

- MAL number

Genotropin 5.3 mg powder and solvent  
for solution for injection-  
MAL20081840AZ

Genotropin 12 mg powder and solvent for  
solution for injection-MAL20081841AZ

**Manufacturer**

Pfizer Manufacturing Belgium N.V.  
Rijksweg 12  
Puurs B-2870

Belgium

**Product Registration Holder**

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